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10/657,249

09/09/2003

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ROGERS1

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EXAMINER

NAFF, DAVID M

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1657

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/657,249 | Applicant(s) ROGERS ET AL. | |
| | Examiner David M. Naff | Art Unit 1657 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6, 8-15 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 2-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-15 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

An amendment of 12/21/07 amended claims 10, 15 and 19.

Claims in the case are 2-6, 8-15 and 19.

Claims 2-6 are withdrawn from further consideration pursuant to
5 37 CFR 1.142(b), as being drawn to a nonelected invention, there being
no allowable generic or linking claim. Applicant timely traversed the
restriction (election) requirement in the reply filed on 4/5/06.

Claims examined on the merits are 8-15 and 19.

The text of those sections of Title 35, U.S. Code not included in
10 this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C.
112:

15 The specification shall contain a written description of the invention, and of the
manner and process of making and using it, in such full, clear, concise, and exact
terms as to enable any person skilled in the art to which it pertains, or with
which it is most nearly connected, to make and use the same and shall set forth the
best mode contemplated by the inventor of carrying out his invention.

20 Claims 8-15 and 19 are rejected under 35 U.S.C. 112, first
paragraph, as failing to comply with the written description
requirement. The claim(s) contains subject matter which was not
described in the specification in such a way as to reasonably convey
to one skilled in the relevant art that the inventor(s), at the time
25 the application was filed, had possession of the claimed invention.

Support is not found in the specification for a detector as
required by claim 19 containing an indicator that develops color when
acetylcholinesterase is inhibited. There is no description of where

the indicator would be located relative to the sol-gel or membrane, the semipermeable material and acetylcholinesterase. While the specification in paragraphs 0020 and 0021 discloses using in the assay a reagent that develops a visible color, there is no description of this reagent being part of the detector as required by claim 19. The reagent that develops color could be added in the assay after the inhibitor contacts the detector of claim 19 without the reagent being part of the detector of claim 19 before contacting with the inhibitor.

Claim Rejections - 35 USC § 112

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is confusing by not having antecedent basis for "the enzyme assay" (bridging the last two lines). Claim 19 has been amended to delete enzyme. It is suggested "the enzyme assay" be replaced with --- detecting of the acetylcholinesterase inhibitors ---.

Claim Rejections - 35 USC § 103

Claims 9, 10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kok et al (J. Biomater. Sci. Polymer Edn, Vol 12, No. 11, pp. 1161-1176 (2001)) in view of Strobel et al (5,766,473) and Gordon et al (6,541,230) (newly applied).

The claims are drawn to a detector for detecting at least one of organophosphorus or carbamate compounds that are inhibitors of acetylcholinesterase. The detector consists of acetylcholinesterase

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and an indicator that changes color immobilized in a sol-gel or membrane, wherein the acetylcholinesterase is inhibited by the organophosphorus or carbamate. The sol-gel or membrane is packaged in a semipermeable material that controls access of acetylcholinesterase inhibitors. The package can be a semipermeable polyethylene bag which is opened after exposure to the inhibitor to commence the assay.

Kok et al disclose acetylcholinesterase and choline oxidase immobilized in a membrane for use as a biosensor.

Strobel et al disclose storing enzyme-loaded membranes in a polyethylene bag (col 33, lines 43-45).

Gordon et al disclose using an indicator that changes color in combination with acetylcholinesterase (abstract and col 7, lines 16-40).

It would have been obvious to store the membrane containing acetylcholinesterase disclosed by Kok et al in a polyethylene bag as suggested by Strobel et al storing an enzyme-containing membrane in a polyethylene bag. It would have been obvious to use a semipermeable polyethylene bag when desiring to contact the acetylcholinesterase with the inhibitor while in the bag. Using the bag for both storage of the immobilized acetylcholinesterase and contacting with the inhibitor would have been obvious to obtain use of the bag for both functions. Acetylcholinesterase is not oxygen sensitive, and when storing acetylcholinesterase in the bag, protecting from oxygen as disclosed by Strobel et al would obviously not be required. It would have been further obvious to omit choline oxidase from the membrane of

Kok et al when the function of the choline oxidase is not needed. The acetylcholinesterase of Kok et al will inherently be inhibited by organophosphorus or carbamate compounds. Providing a reagent that develops color would have been suggested by Gordon et al when
5 performing an assay in regard to detecting the activity of acetylcholinesterase.

Claim Rejections - 35 USC § 103

Claims 8 and 14 are is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 9, 10 and 19
10 above, and further in view of Stanford et al and Avnir et al.

Claim 8 requires the acetylcholinesterase to be immobilized in a sol-gel, and claim 14 requires the sol-gel to be in a tube.

Stanford et al disclose acetylcholinesterase immobilized in a sol-gel film on electrodes. For example, see claim 9.

15 Avnir et al disclose entrapping enzymes in a sol-gel glass (paragraph bridging cols 4 and 5) for use as a biosensor (col 5, lines 14-15). The sol-gel containing the immobilized enzyme can be formed in a tube (col 7, line 17).

When modifying Kok et al as suggested by Strobel et al as set
20 forth above, it would have been obvious to substitute for the membrane of Kok et al a sol-gel as suggested by Stanford et al and Avnir et al for immobilizing acetylcholinesterase. It would have been further obvious to form the sol-gel in a tube as suggested by Avnir et al forming the sol-gel in a tube.

Claim Rejections - 35 USC § 103

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 8 and 14 above, and further in view of Charych et al (6,485,987 B1).

5 The claim requires the sol-gel to be a glass prepared from tetramethylorthosilicate.

Charych et al disclose preparing a sol-gel glass from tetramethylorthosilicate (paragraph bridging cols 2 and 3) for use as a detection means (col 3, line 43).

10 When modifying Kok et al as suggested by references as set forth above, it would have been obvious to produce the sol-gel as a glass using tetramethylorthosilicate as suggested by Charych et al.

Claim Rejections - 35 USC § 103

15 Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claim 11 above, and further in view of Khue et al (5,624,831).

The claims require the acetylcholinesterase in the sol-gel to be stabilized with a sugar, which can be trehalose.

20 Khue et al disclose that trehalose is a sugar used to stabilize enzymes (col 3, line 31), and using trehalose to produce stabilized acetylcholinesterase (paragraph bridging cols 3 and 4).

When modifying Kok et al as suggested by references as set forth above, it would have been obvious to use trehalose to stabilize acetylcholinesterase as suggested by Khue et al.

Claim Rejections - 35 USC § 103

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 8 and 14 above, and further in view of Magdassi et al (6,303,149 B1).

5 The claim requires sol-gel particles from 230-400 mesh.

Magdassi et al disclose sol-gel particles containing enzymes (col 2, lines 38 and 44-56, and col 3, lines 34-67).

When modifying Kok et al as suggested references above, it would have been obvious to produce the sol-gel as particles as suggested by
10 Magdassi et al. Selecting a preferred particle size would have been a matter of choice within the skill of the art.

Response to Arguments

The amendment urges that claim 19 has been amended to require an indicator that develops color. However, such an indicator would have
15 been obvious from Gordon et al. The amendment urges that the polyethylene bag of Strobel et al is not semipermeable. However, it would have been obvious to use a semipermeable bag when desiring to contact the acetylcholinesterase with the inhibitor while the acetylcholinesterase is in the bag. Acetylcholinesterase is not
20 oxygen sensitive, and protecting from oxygen as disclosed by Strobel et al would not be required when the enzyme is acetylcholinesterase. The omission of choline oxidase when its function is not desired would have been obvious.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension
5 of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after
10 the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX
15 MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

20 If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M. Naff/
Primary Examiner, Art Unit
1657

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